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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,179	07/02/2003	Roland Kreutzer	A2038-706120	5239

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EXAMINER	
CHONG, KIMBERLY	
ART UNIT	**PAPER NUMBER**
1635	

NOTIFICATION DATE	DELIVERY MODE
12/17/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/612,179	KREUTZER ET AL.	
	Examiner	Art Unit	
	KIMBERLY CHONG	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,6-9 and 16-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,6-9 and 16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/28/09, 08/05/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 08/05/2009 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 05/01/2009 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 08/05/2009, 4, 6-9 and 16-18 are pending in the application.

Claim Rejections - 35 USC § 112 - maintained

Claims 4 and 6-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

Applicant's arguments filed 08/05/2009 have been fully considered but they are not persuasive. Applicants maintain the specification shows possession of a 21 base pair dsRNAs lacking a linkage and the example at page 17, lines 9-27 provides an example of a dsRNA 21 base pairs in length. Applicant is correct in that the specification on page 17 provides support for 21 base pair dsRNA but the strands of the dsRNA are chemically linked. There is no support on page 17 or any other page in the specification that shows applicant was in possession or even contemplated a 21 base pair dsRNA having non-linked strands.

As stated previously the specification discloses on page 4 that the dsRNA of the instant invention has 10 to 1,000, preferably 15 to 49, base pairs. Applicants have exemplified the use of a 21 base pair dsRNA in Example 2, pages 17-19 to demonstrate that shorter dsRNA molecules are capable of RNAi, however it is clearly stated that this result was found when the strands were chemically linked:

> [Page 19, lines 15-18] This result demonstrates that even shorter dsRNAs can be used for specifically inhibiting gene expression in mammals when the double strands are stabilized by chemically linking the single strands.

Thus, it is clear from the specification that one of ordinary skill in the art upon reading the specification would clearly see that a 21 base pair dsRNA could be used for RNAi however this dsRNA must be chemically linked to be effective.

Applicant reiterates their argument that support for the claims can be found at page 4, line 26. As stated previously, the portion of page 4 referred to in the remarks (page 4, line 26) refers to two separate RNA strands, however this disclosure is in the context of "a region II which is complementary within the double stranded structure". There is no disclosure within the specification of the relationship between complementary region I and this "region II" such that the skilled artisan would recognize that this disclosure of separate RNA strands refers to the preferred 15-49 bp dsRNA. There is no support that shows applicant was in possession or even contemplated a 21 base pair dsRNA having non-linked strands.

Applicant agues that the specification describes the dsRNA such that it "can" have strands that are chemically linked which mean the dsRNA can have a further linkage but in other embodiments it will not have even one. The discloser spanning the last paragraph on page 4 to page 5 discusses the advantages of chemically linking the strands of the dsRNA and given that the specification has an embodiment of a 21 base pair linked dsRNA and makes a statement that for this size dsRNA to be effective, it should be linked would mean that Applicants contemplated a 21 base pair dsRNA that is chemically linked. There is no other recitation of a non-linked dsRNA nor is there a specific embodiment of a 21 base pair dsRNA comprising non-linked strands such that one of ordinary skill in the art would believe Applicant had possession of a 21 base pair non-linked dsRNA.

While applicants assert the specification, plainly on its face, shows possession of 21 nucleotide dsRNAs lacking a linkage, they do not point to where this embodiment appears. Applicant is relying on the specific embodiment of a 21 base pair dsRNA as support for the invention as now claimed and this embodiment clearly has linked strands and even more clearly states how important these strands are for the observed result of gene expression interference.

The rejection is therefore maintained and because the claims are considered new matter they do not receive the benefit of the earlier filed priority application PCT/DE00/00244.

Claim Rejections - 35 USC § 102 and 103 - maintained

The rejections of claims 4 and 6-9 under 35 U.S.C. 102(b) as being anticipated by Elbashir et al. (Nature 2001, of record) Tuschl et al. (WO 02/44321, of record) are maintained for the reasons of record. As stated above, these references are considered prior art as the claims do not receive the benefit of the earlier filed priority documents.

The rejection of claims 4 and 6-9 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Crooke (US 6,107,094, of record) is maintained for the reasons of record.

Applicant's arguments are not found persuasive because Crooke et al. clearly teach a dsRNA meeting the claim limitations and as explained previously that while Crooke does not explicitly disclose that these RNAs will inhibit gene expression given the prior art meets all structural limitations of the claims it would, absent evidence to the contrary, be expected to inhibit gene expression. At column 14, Crooke discloses that his oligonucleotides are preferably from 15-25 nucleotides in length. Given the small size of the preferred genus of compounds, the skilled artisan would immediately envisage compounds of each length from 15-25 nucleotides, including 21 nucleotides. Moreover, in the alternative, because Crooke teaches double stranded oligomeric compounds of 20 nucleotides in length that are useful as artificial enzyme substrates and further teaches that the preferred length of his oligomeric compounds is 15-25 nucleotides, one of ordinary skill in the art would recognize production of an artificial substrate of 21 nucleotides to be a matter of design choice.

Thus, Crooke anticipates or renders obvious claims 4 and 6-9.

The rejection of claims 16-18 under 35 U.S.C. 103(a) as being unpatentable over Agrawal et al. (WO 94/01550, of record) is maintained for the reasons of record.

Applicants reiterate their argument over Agrawal by asserting this reference is clearly about oligonucleotides having a hairpin structure and one of ordinary skill in the art would not read Agrawal et al. to suggest an oligoribonucleotide consisting of two separate complementary oligoribonucleotide strands (dsRNA). Applicants further argue that Agrawal et al. teachings require that the self-complementary region and the claimed dsRNA do not include a self-complementary region.

This is not persuasive because the interpretation applicants give to the reference's teachings is not consistent with Agrawal et al. itself. Agrawal et al. clearly teach that the self-complementary region and the target hybridizing region can be connected by a non-nucleotide linker but does not teach the self complementary region does not hybridize with the target complementary region. Figure 1 shows in cartoon form the self-complementary region, represented by circles, base-pairing with the target hybridizing region represented by squares. Further, Agrawal et al. explicitly teach that "the intramolecular base pairing can be so extensive as to involve every nucleotide of the oligonucleotide", which would not be possible if the self-complementary region was unable to hybridize with the target hybridizing region.

Thus, claims 16-18 would have been obvious, as a whole, at the time the invention was made.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Thursday between 6 and 3 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact Tracy Vivlemore at 571-272-2914. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1635